REMARKS

The presently claimed invention features isolated nucleic acid probes which bind selectively to a variant human cytochrome P-450 (CYP3A4) gene having a T to C variance at nucleotide 732 or a isolated nucleic acid probe completely complementary thereto. The probes include at least 7 nucleotides. Such probes are useful for identifying which of the several alleles of the CYP3A4 is present in a patient.

Rejections Under 35 U.S.C. §112 (first paragraph)

The Examiner rejected claims 1-14 as allegedly not enabled. Applicant respectfully traverses this rejection.

The Examiner cited several references as teaching that certain variances in the CYP3A4 gene as being associated with altered drug metabolism and altered risk for a variety of cancers. According to the Examiner, one skilled in the art would not know how to make and use the presently claimed invention because "there is no evidence provided from the specification that the claimed variances ... especially a T to C at position 732 of the CYP3A4 gene are capable of the same function of the variances recited in the prior art." The Examiner goes on to state that there is no evidence that "the claimed variances are indeed functional."

As the Examiner concedes, alterations in the CYP3A4 gene can influence drug metabolism. For this reason, it can be important to test a patient in order to determine which of the several known alleles of the CYP3A4 gene is present in the patient. This testing can entail direct testing for whether a particular variance is present. However, it can also entail analyzing other portions of the gene that are specific to a given allele (haplotyping). Thus, probes specific for a particular variance are useful for allele identification that can indirectly determine whether a variance that has an important functional impact is present.

The current claims are drawn to probes that are specific for a particular variance in the CYP3A4 gene. Because the probes are specific for a particular variance in the CYP3A4 gene, they can be used for allele identification. As the Examiner admits, it is useful to determine which particular allele of the CYP3A4 gene a particular patient possesses. The presently claimed probes are useful for this exact purpose. Thus, Applicant submits that the present claims are enabled and requests that the rejections under 35 U.S.C. §112, first paragraph be withdrawn.

Rejections Under 35 U.S.C. §112 (second paragraph)

The Examiner rejected claim 1-14 as allegedly indefinite. The Examiner stated that the claims were indefinite for using the term "complementary". The Examiner suggested that the claims be amended to employ the term "completely complementary." Applicant has amended the claims as suggested by the Examiner and respectfully requests that this rejection be withdrawn.

Rejections Under 35 U.S.C. §102(b)

The Examiner rejected claims 1-14 as allegedly anticipated by Brennan (U.S. Patent 5,474,796). According to the Examiner, Brennan discloses "a nucleic acid probe array comprising nucleotide sequences comprising every possible permutation of a target nucleic acid wherein the nucleotide sequences are 10 nucleotides in length."

The disclosure of Brennan is akin to the disclosure of a generic chemical formula that encompasses a huge number of compounds. In the case of all possible 10 mer nucleic acid molecules, there are more than one million different sequences. "The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious." *In re Baird* 16 F.3d 380 (Fed. Cir. 1994). The present situation is similar. Brennan essentially discloses a generic formula for all possible 10 mer nucleic acid molecules. Such a teaching cannot properly be seen as anticipating or rendering obvious every possible nucleic acid molecule that has at least 7 nucleotides.

Rejections Under 35 U.S.C. 102(a)

The examiner rejected claims 1-5, 8, 9 and 11-13 as allegedly anticipated by Lichter (WO 99/13106). According to the Examiner, Lichter teaches nucleic acid molecules that bind under selective conditions to a nucleic acid molecule comprising at least one variance in the CYP3A4 gene. However, the Examiner has not pointed to a disclosure in Lichter of a T to C variance at nucleotide 732 of the CYP3A4 gene. Thus, Lichter cannot anticipate all of the elements of the present claims.

Rejections Under 35 U.S.C. 102(e)

The Examiner rejected claims 1-5 and 11-13 as allegedly anticipated by Sinnett et al. (U.S. Patent No. 6,183,963). According to the Examiner, Sinnett et al. teaches nucleic acid molecules that bind under selective conditions to a nucleic acid molecule comprising at least one variance in the CYP3A4 gene. However, the Examiner has not pointed to a disclosure in Sinnett et al. of a T to C variance at nucleotide 732 of the CYP3A4 gene. Thus, Sinnett et al. cannot anticipate all of the elements of the present claims.

The Examiner rejected claims 1-5 and 11-13 as allegedly anticipated by Housman et al. (U.S. Patent No. 6,200,754). According to the Examiner, Housman et al. teaches nucleic acid molecules that bind under selective conditions to a nucleic acid molecule comprising at least one variance in the CYP3A4 gene. However, the Examiner has not pointed to a disclosure in Housman et al of a T to C variance at nucleotide 732 of the CYP3A4 gene. Thus, Housman et al cannot anticipate all of the elements of the present claims.

Conclusion

Applicant asks that all claims be allowed. Enclosed is a $460 check for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 28 FEB 2002

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